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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/837,301	04/11/97	STEVEN A	14014.0327

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EXAMINER	
COOK, L	
ART UNIT	PAPER NUMBER
1641	18

DATE MAILED: 07/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	08/837,301	STEVEN ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-97* is/are pending in the application.

4a) Of the above claim(s) *68-97* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *57-97* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

DETAILED ACTION

Amendment Entry

1. Applicants' response to the Office Action mailed September 25, 2001 (Paper #16, filed 3/30/01) is acknowledged. In response to amendment-B filed therein, claims 57 and 63 were amended. Currently, claims 57-67 are pending and under consideration.

OBJECTIONS WITHDRAWN

Sequence Non-compliance

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Applicant is given THREE MONTHS from the mailing date of this communication within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply. A diskette containing the Sequence Listing has been submitted and entered. This objection is withdrawn.

OBJECTIONS MAINTAINED

Specification

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. The disclosure is objected to because of the following informalities: The first page of the specification is not numbered. Appropriate correction is required.

Drawings

4. The drawings in this application are objected to by the Draftsperson under 37 CFR 1.84 or 1.152 (see PTO-948). Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner. Applicant has deferred response to this objection until the instant application is allowed. Objection is maintained.

Information Disclosure Statement

5. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the Examiner on form PTO-892 or Applicant on form PTO-1449 has cited the references they have not been considered.

Oath/Declaration

6. A new oath or declaration is required because:

A. Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). Please see the entries for citizenship for each inventor.
B. Applicant has not given a post office address anywhere in the application papers as required by 37 CFR 1.33(a), which was in effect at the time of filing of the oath or declaration. A statement over applicant's signature providing a complete post office address is required.
C. The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 601.01(a). Please check the appropriate line.

The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02. Applicant will submit a new Declaration to overcome the objections. Until receipt and consideration of the new Declaration the objection is maintained.

REJECTIONS WITHDRAWN

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 57-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 57 is vague and indefinite because it is unclear as to what the term "comprising" entails. The claim recites a composition containing a T4 surface lattice protein and a chimera comprising. Is this wording referring to only the chimera composition or is it referring to the composition of both the T4 surface lattice protein and the chimera? Please explain.

B. Claim 63 ambiguous in utilizing the phrase "encodes a dispensable polypeptide". The recited claim is unclear because it is not known if the composition contains more than one dispensable polypeptide? (i.e. the dispensable polypeptide derived from a member of the T4 virus family that encodes a [second] dispensable polypeptide). Please clarify.

Response to Arguments

Claims 57-67 are withdrawn from rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The amendments to the cited claims have sufficiently clarified claim language.

Claim Rejections

8. With respect to the claim rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a), Applicant argues that the reference by MacDonald et al. (Embro Journal, 12/1984, Vol.3, No.12, pages 2863-2871)-ABSTRACT ONLY does not anticipate the instant invention because it merely teaches the genetic location of three separate genes on the standard phage T4 genetic map but does not disclose a chimera composition as defined by the instant claims. Applicant's arguments have been fully considered and found persuasive. The following rejections are withdrawn.

I. Claims 57, 62, 63, 64, 66, and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Macdonal et al. (Embro Journal, 12/1984, Vol.3, No.12, pages 2863-2871)-ABSTRACT ONLY.

II. Claims 58, 59, 60, 61, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macdonal et al. (Embro Journal, 12/1984, Vol.3, No.12, pages 2863-2871)-ABSTRACT ONLY in view of U. Aebi et al. (J. Mol. Biol., 1977, 110, pages 687-698) and Ladner et al. (USP#5,403,484).

REJECTIONS MAINTAINED

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 57-67 are rejected under 35 U.S.C. 102(a) as being anticipated by Ren et al. (Protein Science (1996), Vol.5, pages 1833-1843).

Ren et al. teach compositions in which molecules of interest are displayed through polymer binding. The polymers are T4 capsids and polyheads (tubular capsid variants) and the display molecules are derivatives of the dispensable capsid protein SOC. (Abstract). In figure 1, on page 1834 – the principle of the SOC display system is outlined. A surface lattice of the T4 capsid contains two dispensable proteins, SOC and HOC (claims 64 and 65). The surface lattice protein is a hexagonal array of hexamers of protein gp23*. HOC and SOC bind to the outer surface of the gp23* lattice: a HOC monomer binds at the center of each hexamer, and trimers of SOC bind around the trigonal sites. Peptides or polypeptides (examples with 4-residue and 316-residue peptides are shown) are expressed/displayed as C-terminal fusions of SOC and bind to the display platform. The mature surface lattice does not dissociate over a wide range of concentrations and environmental conditions. The composition is taught to be suitable in expressing an antigen (see page 1838), an enzyme see page 1839-(induce T-cell response), and an immunoglobulin (see page 1836-Immunogenicity of SOC-V3 phage). Also see page 1839-Potential application of the SOC system.

Response to Arguments

Applicant argues that the cited reference lists co-inventors and is properly cited. Accordingly applicant will file a Katz-type declaration to resolve the issue. The rejection is maintained.

NEW GROUNDS OF REJECTION NECESSITATED BY AMENDMENT

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 57, 62, 63, 64, 66, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ladner et al. (USP#5,403,484) in view of Macdonal et al. (Embro Journal, 12/1984, Vol.3, No.12, pages 2863-2871)-ABSTRACT ONLY.

Ladner et al. (USP#5,403,484) show that viruses expressing chimeric binding proteins can be useful in producing novel enzymes and hormones. (column 16, lines 1-8). Novel binding proteins against a molecule of interest encoding a protein comprising a binding domain are utilized to display a protein on the outer surface of a chosen bacterial cell, spore, or phage. See abstract.

The protein may be expressed as an insert in a chimeric bacterial outer surface protein (OSP). "All bacteria exhibit proteins on their outer surface". Column 60, lines 58-61. In order to obtain appropriate display it may be necessary to add one or more linkers amino acids between the OSP and the potential binding domain (PBD). Column 71, lines 13-22.

Ladner et al. differ from the instant invention is not specifically employing a T4 phage in the chimeric composition.

However, MacDonald et al. disclose DNA sequence and transcriptional patterns in T4 phage (*T4 surface lattice protein array*). The T4 phage is taught to be a suitable lattice protein in the instant invention. See the specification, page 2, lines 1-2 and page 12, lines 11-18. In an area between 15 and 18 kb on the standard phage T4 map, the novel gene 69 is localized. This 69 gene (*molecule of interest*) codes for two overlapping proteins that share a common C-terminal segment. The two proteins are expressed from different transcripts that are under different regulation. The smaller protein, gp69*, can be expressed from a Escherichia coli-like promoter, but the expression of the larger protein, gp69 is delayed. The gene (69) is bracketed by DNA adenine methylase (*linker*) and the late gene SOC (*T4 dispensable polypeptide*).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the T4 phage surface lattice protein as taught by MacDonald et al. in a chimera composition as disclosed by Ladner et al. to produce outer capsid molecule display, because such T4 phage molecules as taught by MacDonald et al. are well known in the art. A person of ordinary skill in the art would have had a reasonable expectation of success utilizing T4 phage given the knowledge on its detailed structure.

One having ordinary skill in the art would have been motivated to do this because MacDonald et al. taught that the DNA sequence and transcription patterns on the standard phage T4 map is interdigitated in a complex pattern that reveals all elements that are thought to be important in regulation of the T4 gene. See abstract.

II. Claims 58, 59, 60, 61, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ladner et al. (USP#5,403,484) in view of Macdonal et al. (Embro Journal, 12/1984, Vol.3, No.12, pages 2863-2871)-ABSTRACT ONLY and in further view of U. Aebi et al. (J. Mol. Biol., 1977, 110, pages 687-698) and.

Please see discussion of Ladner et al. in view of Macdonald et al. as set forth above.

Ladner et al. in view of Macdonald et al. differ from the instant invention in failing to teach the dispensable polypeptide-HOC and the different types of molecules of interest that may be expressed in this system (antigen, enzyme, or immunoglobulin).

However, U.Aebi et al. disclose that the T4 phage has two dispensable capsids namely, soc and hoc. (page 687)

Ladner et al., Macdonald et al., and U. Aebi et al. are all analogous art because they are from the same field of endeavor, all three inventions teach expression techniques involving phage display.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the HOC as a dispensable polypeptide and express antigens, enzymes, or immunoglobulins as specific molecules of interest as taught by U. Aebi et al. in the method of Ladner et al. in view of Macdonald et al. to perform outer capsid phage display, because such dispensable polypeptides and molecules of interest as taught by U. Aebi et al. are well known in the art. A person of ordinary skill in the art would have had a reasonable expectation of success utilizing such materials, because they were already shown to be operable in the prior art.

One having ordinary skill in the art would have been motivated to do this because U. Aebi et al. taught that compositions comprising soc and hoc lattices are much more stable. See page 697, 2nd paragraph.

Response to Arguments

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to the argument that Ladner et al. only discloses compositions wherein the molecule of interest is fused directly to a coat protein and is not linked by a linker, applicant is directed to sections Column 71, lines 13-22 of U.S. Patent #5,403,484. "In order to obtain appropriate display it may be necessary to add one or more linkers amino acids between the OSP and the potential binding domain (PBD)".

Applicant contends that one of ordinary skill would not be motivated to link the dispensable polypeptides to another molecule via a linker and still retain the ability to bind intact phage. However, U. Aebi et al. taught that compositions comprising soc and hoc (dispensable polypeptides) and the lattices are much more stable and do not adversely effect phage display.

Given this teaching, one would be motivated to linking molecules of interest to the dispensable polypeptides in order to increase stability of the construct against dissociation and elevated temperatures while preserving the phage display capacity. See U. Aebi et al. page 697, 2nd paragraph.

11. For reasons aforementioned, no claims are allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action.

In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Lisa V. Cook
CM1-7B17
(703) 305-0808
6/26/01

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/1641